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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,783	12/08/2003	L. Dean Parks	1238.009	4821
27353	7590	08/25/2006	EXAMINER	
MELVIN K. SILVERMAN 500 WEST CYPRESS CREEK ROAD SUITE 500 FT. LAUDERDALE, FL 33309			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/730,783

Applicant(s)

PARKS, L. DEAN

Examiner

Vickie Kim

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Copy of Bib sheet.

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. 120 and 37 CFR 1.78. This application discloses and claims only subject matter disclosed in earliest prior Application No. 09/605747, filed 6/29/2000, now patented US 6,319,945 and names an inventor or inventors named in the prior application.

Accordingly, this application has the benefit of the filing date of the prior application.

### ***Status of Application***

1. The claims are pending and presented for the examination.
2. Bib Sheet information has been corrected where inadvertent error was been shown. For example, in continuing data section, in 7<sup>th</sup> line, the phrase "which is a CIP of 09/967915 10/02/2001 PAT 6,4229,160" has been rewritten with corrected data "which is a CIP of 9/976915 10/12/2001 PAT 6,399,651".

Correction is made into the Bib sheet and a copy of corrected Bib sheet is enclosed.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1618

2. Claims 1-5, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Komer (US 5773422).

The claims are drawn to a topical composition comprising an avermectin compound and a pharmaceutically acceptable carrier, where amount of avermectin compound is present in a concentration range from about 0.05 to 0.5%(w/v).

Komer(US'422, hereinafter) teaches avermectin formulation including topical formulation such as transdermal patch or topical pour-on formulation, see abstract ; col. 2, line 15 and col.4, lines 19-20. Especially, topical pour-on composition is exemplified where the composition comprising 5mg/ml(converted to 0.5% w/v) ivermectin, propylene glycol or water as carrier. US'422's formulation includes 0.1 to 40%(w/v) avermectin such as ivermectin, see col. 3, lines 6-7.

Claims 7-10 require kit comprising a dermatological composition comprising an avermectin intergrated in one form of dermal patch. US'422 teaches avermectin included in transdermal patch, see col.4, lines 19-20.

It is noted that the intended use recited in the claims are considered but the claims are properly included in this rejection because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Art Unit: 1618

MPEP 2100 also states that an old product into a kit will not render the claimed invention nonobvious even if the instructions detail a new use for the product). In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983).

All the critical elements required by the instant claims are well taught and thus, all the claims are clearly anticipated by Komer reference(US'422).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (US '422) alone.

The claim 6 is drawn a topical composition comprising an avermectin compound and a pharmaceutically acceptable carrier such as soap or shampoo, where amount of avermectin compound is present in a concentration range from about 0.05 to 8%(w/v).

US'422 teaches a carrier including solvent and surfactant(see col.2, line 40-42), and also formulation in presence of detergent (see col.3, line 20). Surfactant and detergent are readily understood as basic ingredients soap or shampoo formula, and thus one would have been readily substitute surfactant or detergent with soap or shampoo formula when Komer's patent is learned.

5. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated or alternatively under 103(a) as being unpatentable over Miller (US5728719).

Art Unit: 1618

Miller(US'719, hereinafter) teaches a topical application containing avermectin compound such as ivermectin, see abstract; col. 9, lines 17; and col. 10, lines 30-32, 40 and 51. At example 10, the patented composition(col. 14 lines 35) is contemplated in transdermal gel formulation which comprises a combination of nitrogen containing heterocyclics and avermectin compound(see col. 15, lines 4-5). Based on Miller's teaching, one would have been easily calculated the effective amount of avermectin included in combination. For example, primary ingredient(i.e. nitrogen containing heterocyclics) is present in about 5%(50mg/g), and second ingredient such as avermectin compound is present in about 0.005-0.5%( $10^{-1}$  to  $10^{-3}$  of primary ingredient, see col. 10, lines 59-61 and col. 14, lines 56-57).

Although US'719 does not explicitly state the percentage of amount of avermectin in w/v, the claimed subject matter(i.e avermectin in 0.05-0.5%) is readily envisaged by or apparent to one of ordinary skill in the art because US'719 indirectly teaches an amount of avermectin compound as set forth immediately above. Furthermore, titration of optimal dose would be considered to be routine practice which does not render claimed invention patentably distinct over the prior art of the record, because the topical combination composition of Miller patent clearly suggests possible dosage range of effective amount of avermectin in his patented disclosure.

As mentioned earlier in 102 and 103 rejection above(supra), the intended use recited in the claims are considered but the claims are properly included in this rejection because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

Art Unit: 1618

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Also, a kit will not render the claimed invention nonobvious. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983).

Therefore, all the claims are properly included in this rejection as being anticipated or being obvious over prior art of the record.

### ***Conclusion***

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Hartley reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/730,783

Page 7

Art Unit: 1618

A handwritten signature in black ink, appearing to read 'Vickie Kim', with a large, sweeping loop at the end.

**VICKIE KIM  
PRIMARY EXAMINER**

Vickie Kim  
Primary Patent Examiner  
Art Unit 1618